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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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MAR 1993

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT **2-Ethylhexyl Ester of 2,4-Dichlorophenoxyacetic acid:** Industry Task Force II on 2,4-D Research Data.

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STUDY IDENTIFICATIONS:

Submission: S433 **DP Barcode: D186733** **PC Code: 030063**

Caswell No. 315 AS **MRID No. 426052-02**

Registrant: Industry Task Force II on 2,4-D Research Data

ACTION REQUESTED: Review of an acute inhalation toxicity study with **2-EHE-2,4-D.**

SUMMARY: The acute inhalation toxicity of 2-ethylhexyl ester of 2,4-dichlorophenoxyacetic acid [95.1%; 63.1% acid equivalent], was evaluated in male and female Fischer 344 rats. The limit test concentration of 5.39 mg/L for 4 hours produced no compound-related toxicity. The inhalation LC_{50} was > 5.39 mg/L.

TOXICITY CATEGORY: IV

CORE CLASSIFICATION: **Guideline**; satisfies Guideline requirement [81-3] for an acute inhalation toxicity study and is acceptable for regulatory purposes.

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PRIMARY REVIEWER: Jess Rowland, Toxicologist
Section II, Toxicology Branch II

SECONDARY REVIEWER: K. Clark Swentzel, Section Head
Section II, Toxicology Branch II

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DATA EVALUATION REPORT

STUDY TYPE: Acute Inhalation Toxicity **GUIDELINE: 81-3**

Submission: S433527 **DP Barcode: D186733** **PC Code: 030063**

Caswell No. 315 AS **MRID No. 426052-02**

TEST MATERIAL: 2-Ethylhexyl Ester of 2,4-Dichlorophenoxyacetic acid

REGISTRANT: Industry Task Force II on 2,4-D Research Data

TESTING LABORATORY: The Toxicology Research Laboratory, The Dow Chemical Co, Midland, Mi

STUDY IDENTIFICATION: K-020054-015

TITLE OF REPORT: 2,4-Dichlorophenoxyacetic acid, 2-ethylhexyl ester: Acute aerosol inhalation toxicity study with Fischer 344 rats.

AUTHOR: F. S. Cieszlak

REPORT DATE: December 22, 1992

CONCLUSION: The acute inhalation toxicity of 2-ethylhexyl ester of 2,4-dichlorophenoxyacetic acid [95.1%; 63.1% acid equivalent], was evaluated in male and female Fischer 344 rats. The limit test concentration of 5.39 mg/L for 4 hours produced no compound-related toxicity. The inhalation LC_{50} was > 5.39 mg/L.

TOXICITY CATEGORY: IV

CORE CLASSIFICATION: **Guideline;** satisfies Guideline requirement [81-3] for an acute inhalation toxicity study and is acceptable for regulatory purposes.

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I. INTRODUCTION

This Data Evaluation Report (DER) summarizes the experimental procedures and results of an acute inhalation toxicity study of 2-ethylhexyl ester of 2,4-D [2,4-D-EHE] in rats.

II. MATERIALS AND METHODS

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1. Test Material

Common Name:	2,4-D-EHE
Active Ingredient:	**2-ethylhexyl ester of 2,4-D Acid**
Purity;	95.1%
Composition:	63.1% 2,4-D acid equivalent
Batch/Lot No:	Lot #04KF54479.
Description:	Amber/dark liquid
Vapor pressure:	3.6×10^{-6} mmHg at 25°C

2. Test Animals

Species:	Rats
Strain:	Fischer 344
Sex:	Males and Females
Age:	≈ 10 weeks at initiation
Identification:	Ear tags.
Acclimation:	at least 1 week

3. Animal Husbandry

Housing:	1/cage.
Food:	Purina Certified Rodent Chow #5002 ad libitum
Water:	tap water ad libitum
Environment:	Temperature- 22 ± 2°C; Humidity- 40-60%

4. Exposure Procedure

Liquid aerosols of 2,4-D-2-EHE were generated and the test material was mixed with compressed air in a spray nozzle. The resulting aerosol was sprayed into a 42 liter chamber to which compressed air was supplied and controlled by a system designed to maintain temperature at approximately 22°C. The air flow was maintained 30 liters/ minute, which was adequate to provide the normal concentration of oxygen to the animals. The air flow through the chamber was determined with a manometer. Ambient room temperature, chamber humidity and chamber air flow were recorded every 30 minutes.

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The mass concentration of aerosol present in the chamber was determined gravimetrically four times during the exposure, the time-weighted average exposure concentration was calculated from these gravimetric measurements, and the nominal concentration was determined based on the amount of test material used and the total chamber airflow. Particle size determination were made twice using a Cascade Impactor.

A group of five rats/sex were exposed nose-only for a single-four hour duration to aerosol concentration of the test material targeted at 5.39 mg/mL [slightly excess than the limit dose]. Animals were observed during the exposure period and daily during the two-week post exposure period. Body weights were obtained on Days 2, 4, 8, 11 and 15. The eyes of each rat were examined with a pen light both prior to exposure and prior to necropsy. Rats were sacrificed and a complete necropsy was performed.

5. Regulatory Compliance

A signed Statement of No Data Confidentiality Claim was provided that was dated December 17, 1992.

A signed statement dated 12/21/92 indicated that this study conformed to the principles of EPA's Good Laboratory Practice Standards.

A Quality Assurance statement dated 12/22/93 was provided.

III. RESULTS

1. Chamber Atmosphere Conditions During Exposure

Exposure Time [Min]	Concentration [mg/L]	Temperature	Relative humidity %	Time Weighted Average [mg/L]	Nominal Concentration [mg/L]
45	5.22	-	-	-	-
109	5.45	-	-	-	-
137	5.57	-	-	-	-
200	5.35	21.6°	26.4	5.39	6.89

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2. Particle Size

The mass median aerodynamic diameter (MMAD) of the aerosol was 1.96 μm, with a geometric standard deviation of 2.17. Approximately 19% of the total particle mass was less than 1 μm in size and 73% of the total mass was <3 μm.

3. Animal Data

All rats survived the exposure and appeared to be normal throughout the two-week observation period. Following a slight weight loss, 2% in males on Day 2 and 1% in females on Day, animals subsequently gained weight during the observation period. No ophthalmologic abnormalities were observed. No treatment-related gross pathological changes were seen.

IV. CONCLUSION

A four-hour nose only exposure of aerosols of the 2-ethylhexyl ester of 2,4-dichlorophenoxyacetic acid at 5.39 mg/L to male and female Fischer 344 resulted in no exposure-related effects. The inhalation LC_{50} was > 5.39 mg/L.

TOXICITY CATEGORY: IV

V. CORE CLASSIFICATION:

Guideline; satisfies Guideline requirement [81-3] for an acute inhalation toxicity study and is acceptable for regulatory purposes.

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(NEW INPUT)

Tox Chem No. 315 AS File Last Updated _____ Current Date 2/24/93

STUDY/LAB/STUDY #/DATE	MATERIAL	EPA MRID NO.	RESULTS: LD50, LC50, PIS, NOEL, LEL	TOX CATEGORY	CORE GRADE/DOC. #
81-3 Acute Inhalation Species: Rat Dow.Tox.Res.Lab. 12/22/92:K-020054-015	2,4-D IOE 95% purity 63.1% acid equivalent	426052-02	LC_{50}= >5.39 mg/L. (only concentration tested)	IV	Guideline

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END